



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

The Tobacco Products Scientific Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: The Tobacco Products Scientific Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 9, 2015, from 8:30 a.m. to 5 p.m. and April 10, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at:

<http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

Contact Person: Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 1-877-287-1373, email: [TPSAC@fda.hhs.gov](mailto:TPSAC@fda.hhs.gov). A notice in the Federal Register about last minute modifications that impact a previously announced

advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 9 and 10, 2015, the Committee will discuss modified risk tobacco product applications submitted by Swedish Match North America Inc. for 10 tobacco products:

- MR0000020: General Loose, smokeless tobacco, loose snus, 1.59 oz (45g), cardboard can (SKU 4852);
- MR0000021: General Dry Mint Portion Original Mini, smokeless tobacco, snus portions, 0.21 oz (6g), 20 0.3g portions, plastic can (SKU 4800);
- MR0000022: General Portion Original Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4880);
- MR0000023: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15 0.9g portions, plastic can (SKU 4877);
- MR0000024: General Classic Blend Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12 0.9g portions, plastic can (SKU 4878);
- MR0000025: General Mint Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4352);
- MR0000026: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.48 oz (13.5g), 15 0.9g portions, plastic can (SKU 4876);
- MR0000027: General Nordic Mint Portion White Large, smokeless tobacco, snus portions, 0.38 oz (10.8g), 12 0.9g portions, plastic can (SKU 4875);

- MR0000028: General Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4881); and
- MR0000029: General Wintergreen Portion White Large, smokeless tobacco, snus portions, 0.9 oz (24g), 24 1g portions, plastic can (SKU 4882).

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: On April 9, 2015, from 8:30 a.m. to 4 p.m. and on April 10, 2015, from 8 a.m. to 5 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 20, 2015. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 p.m. on April 10, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 12, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a

lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 13, 2015.

Closed Committee Deliberations: On April 9, 2015, between 4 p.m. and 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (see 5 U.S.C. 552b(c)(3) and (c)(4)). This portion of the meeting will be closed because the Committee will be discussing trade secret and/or confidential data provided by Swedish Match North America Inc.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Caryn Cohen at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 9, 2015.

Leslie Kux,

Associate Commissioner for Policy

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